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## **REMARKS**

Claims 1, 4-5, 8-9, 12-13, 15, and 18-20 are rejected in the last Office Communication, and remain pending.

## 103 Rejection:

Claims 1, 8-9, 11-15 and 17-19 are rejected as obvious over Barsch in view of Fischer and further in view of Burbank. It is respectfully urged that this rejection is improper for at least the following reasons.

It is respectfully urged that the Examiner has not established a *prima facie* case of obviousness, because the prior art reference or combination of references must teach or suggest all of the limitations of the claim. MPEP § 2143.03. It is respectfully urged that even if one combined the references as suggested by the Examiner, the resulting combination would not provide all the limitations of the amended claims.

## Claims 1 and 12

Regarding Claims 1 and 12, the Examiner states that Barsch teaches all the limitations of the claims, except that the Examiner considers Barsch as not teaching "a plunger that is separable into a deployment rod and cutter."

The Examiner addresses this by then stating:

However, Fischer discloses an introduction device comprising a cutter 20 and a deployment rod 22, wherein the deployment rod includes a cutter seat 68 proximate the trailing end configured for abutment with the cutter...

It is respectfully urged that this is not a correct interpretation of Fischer.

First, Fischer does not teach that element 20 of Fischer is a cutter, as the Examiner maintains. Instead, Fischer teaches at col 5, lines 36-42 that:

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The plunger means in turn is comprised of a primary plunger member which is generally designated at 20 and a secondary plunger member which is generally designated at 22.(Italics added).

Also, Fischer does not teach a" cutter seat 68", as the Examiner maintains. Instead, Fischer teaches that:

...the disc 66 is generally circular in configuration, but has four arcuate portions as shown at 68 removed so that the disc 66 does not form a fluidtight fit within the first chamber 25... (see column 6, lines 55-60).

Accordingly, Fischer does not teach or suggest a cutter or a cutter seat as the Examiner maintains. Instead, Fischer teaches that 68 refers to removed portions of a disc.

In addition, Claim 1 recites among other things,

retracting the cutter to expose the proximal opening of the cutter lumen;

inserting the biopsy marker introduction assembly into the proximal opening of the cutter lumen;

The Examiner's rejection states Barsch discloses

"retracting the marker deployment rod 52 to expose the proximal opening of the cutter lumen 16." and

"retracting a cutter 52 to expose a cutter lumen 16 of a biopsy probe 10"

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It is respectfully urged that this is not a correct characterization of Barsch. Element 52 of Barsch is a "plunger 52", not a "cutter 52". See column 5, lines 55-66 of Barsch. See also column 1 of Barsch which discloses a "cutter 26" in reference to Barsch's Figure 1.

It is respectfully urged that the Examiner has misconstrued the element 52 of Barsch as a cutter.

Therefore, even if one combines Fischer and Barsch (and Burbank), the resulting combination would not provide the subject matter of Claims 1 and 12 for the reasons set forth above.

Additionally, Claim 1 recites among other things

distally advancing the cutter to drive the marker deployment rod and thus the marker to cause deployment of the marker through the distal opening of the cutter lumen at the biopsy surgical site.

It is respectfully urged that Barsch and Fischer alone or combined don't teach such a step. Barsch does not teach that the cutter 26 disclosed in Figure 1 of Barsch should be advanced to drive a marker deployment rod. Referring to column 6, lines 55-66 of Barsch, Barsch explains that the plunger 52 is axially advanced to drive the marker 42 out of the aperture 22. It is respectfully urged that Neither Barsch nor Fischer teach or suggest that a cutter (such as the cutter 26 disclosed in Barsch) be advanced to deploy a marker.

Claim 20:

With respect to Claim 20, the Examiner states Barsch discloses:

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A marker deployment rod 52 proximal to the marker 42 and slidingly received in the tube 44, and having a proximal extension 70 configured for abutment with the cutter 52 to deploy the marker.

It is respectfully urged that this is not only an incorrect characterization of Barsch (for the reasons set forth above)...<u>it would appear to be physically impossible!</u>

The Examiner is respectfully requested to explain how the deployment rod 52 can have an extension configured for abutment with itself (even if it is referred to a cutter in the alternative)! The Examiner uses the same reference number 52 to refer to a "deployment rod" and a "cutter". It is respectfully urged that the same element 52 (whatever it is) cannot abut itself.

Accordingly, the Examiner should withdraw the rejection of Claim 20 and all the claims depending therefrom.

It is also respectfully urged that the Examiner has not established a *prima facie* case of obviousness, because there must be some teaching, suggestion, or motivation to modify the references either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art, in order for a *prima facie* case of obviousness to exist. MPEP § 2143.01. The mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP § 2143.01. Actual evidence of a suggestion, teaching or motivation to combine prior art references must be shown. *In re Dembiczak*, 50 USPQ2d 1614 (Fed.Cir. 1999). Broad conclusory statements, standing alone, simply are not evidence. *Id.* Motivation to combine or modify will be lacking if the art teaches away from a claimed combination. MPEP § 2145.

It is respectfully urged that, with respect to all the obviousness rejections, the Examiner has not identified evidence of a suggestion or motivation to modify or combine the teachings of the references as required by MPEP § 2143, but instead has merely reconstructed the claimed invention based on improper hindsight reliance on the Applicant's disclosure.

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In particular, but without limitation, the Examiner is respectfully requested to explain what in the art would motivate one to combine the syringe apparatus of Fischer with Barsch as the Examiner applies those references. Fischer is directed to a syringe with a detachable mixing and delivery tip, not to taking biopsy samples, or to a cutter for obtaining biopsy samples, or to deploying biopsy markers. Barsch is directed to a method and apparatus for deploying a biopsy marker. Fischer does not mention cutters, and Barsch shows a cutter 26, but does not teach or suggest the Barsch deployment apparatus should include a cutter. Accordingly, it is respectfully urged that there is no basis in the references or the prior art for combining the references as the Examiner suggests.

## Conclusion

In light of the remarks made herein, it is respectfully submitted that the claims currently pending in the present application are in form for allowance. Accordingly, reconsideration of those claims, as amended herein, is earnestly solicited.

Respectfully submitted,

/Gerry Gressel/ Gerry Gressel, Reg#34,342

October 19, 2007 (513) 337 3535